



Docket No.: 020187.0100/P-5677
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
James M. Harris et al.

Application No.: 10/825,908

Confirmation No.: 8944

Filed: April 16, 2004

Art Unit: 1637

For: NEISSERIA GONORRHOEAE ASSAY

Examiner: Suchira Pande

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed after the mailing date of a Final Office Action or Notice of Allowance, whichever occurred first, but on or before payment of the Issue Fee (37 CFR 1.97(d)). Applicant(s) hereby petition(s) that the Information Disclosure Statement be considered.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

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In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information

Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Credit Card in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). Credit Card Payment Form SB-2038, with a signature from an authorized cardholder, is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-2228, under Order No. 020187.0100/P-5677.

Dated: January 4, 2007

Respectfully submitted,

By Kellie L. Carden
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Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/825,908-Conf. # 8944
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Filing Date	April 16, 2004
				First Named Inventor	James M. Harris
				Art Unit	1637
				Examiner Name	Suchira Pande
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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	4,683,195	7-28-87	Mullis et al.	
	AB	4,683,202	7-28-87	Mullis	
	AC	4,755,458	7-5-88	Rabbani et al.	
	AD	4,800,159	1-24-89	Mullis et al.	
	AE	4,900,659	2-13-90	Lo et al.	
	AF	4,965,188	10-23-90	Mullis et al.	
	AG	5,102,784	4-7-92	George	
	AH	5,108,895	4-28-92	Woods et al.	
	AI	5,130,238	7-14-92	Malek et al.	
	AJ	5,173,401	12-22-92	Wolff et al.	
	AK	5,256,536	10-26-93	Miyada et al.	
	AL	5,270,184	12-13-93	Walker et al.	
	AM	5,378,606	1-3-95	Stern et al.	
	AN	5,389,515	2-14-95	Chmelo et al.	
	AO	5,427,930	6-27-95	Birkenmeyer et al.	
	AP	5,432,271	7-11-95	Barns et al.	
	AQ	5,453,355	9-26-95	Birkenmeyer et al.	
	AR	5,455,166	10-3-95	Walker	
	AS	5,470,723	11-28-95	Walker et al.	
	AT	5,536,638	7-16-96	Rossau et al.	
	AU	5,550,040	8-27-96	Purohit t al.	
	AV	5,595,874	1-21-97	Hogan et al.	
	AW	5,648,211	7-15-97	Fraiser et al.	
	AX	5,712,124	1-27-98	Walker	
	AY	5,744,311	4-28-98	Fraiser et al.	
	AZ	5,814,490	9-29-98	Spears	
	AA1	5,928,869	7-27-99	Nadeau et al.	
	AB1	5,958,700	9-28-99	Nadeau et al.	
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	AD1	5,962,273	10-5-99	Durmowicz et al.	
	AE1	5,976,805	11-2-99	You	
	AF1	6,316,200	11-13-01	Nadeau et al.	
	AG1	6,379,888	4-30-02	Nadeau	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ^o
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	BA	EP-0 317 077	1-31-96	Urdea et al.		
	BB	EP-0 353 985	2-7-90	Woods et al.		
	BC	EP-0 497 272	8-5-92	Walker		
	BD	EP-0 624 643	11-17-94	Fraiser et al.		
	BE	EP-0 678 582	10-25-95	Nadeau et al.		
	BF	EP-0 684 315	11-29-95	Fraiser et al.		

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	BG	EP-0 747 489	12-11-96	Yang et al.		
	BH	EP-0 823 485	2-11-98	Wyrich et al.		
	BI	WO-89/03891	5-5-89	Urdea et al.		
	BJ	WO-90/10064	9-7-90	Miller		
	BK	WO-91/03573	8-25-90	Kessler et al.		
	BL	WO-94/06817	3-31-94	Chmelo		

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	CA	BARANY, Genetic Disease Detection and DNA Amplification Using Cloned Thermostable Ligase, <i>Proc. Natl. Acad. Sci. USA</i> , 88(1) : 189-93 (1991)			
	CB	BARRINGER et al., <i>Gene</i> , 89 :117-122 (1990)			
	CC	BUIMER et al., Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> by Ligase Chain Reaction-Based Assays with Clinical Specimens from Various Sites: Implications for Diagnostic Testing and Screening, <i>J. Clinical Microbiology</i> , 34(10) :2395-2400 (Oct. 1996)			
	CD	CHAN et al., Performance Characteristics of the Becton Dickinson ProbeTec System for Direct Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in male and female urine specimens in comparison with the Roche Cobas System, <i>Arch. Pathol. Lab. Med.</i> , 124(11) : 1649-52 (2000)			
	CE	CROTCHFELT et al., Detection of <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> in Genitourinary Specimens from Men and Women by a Coamplification PCR Assay, <i>J. of Clinical Microbiology</i> , 35(6) :1536-1540 (June 1997)			
	CF	DONEGAN, JAMES J. Isolation of a species-specific DNA probe for <i>Neisseria gonorrhoeae</i> using a novel technique particularly suitable for use with closely related species displaying high levels of DNA homology, <i>Mol. Cell. Prob.</i> , 3 : 13-26 (1989)			
	CG	GUATELLI et al., Isothermal, in vitro Amplification of Nucleic Acids by a Multienzyme Reaction Modeled After Retroviral Replication, <i>Proc. Natl. Acad. Sci. USA</i> , 87(5) : 1874-8 (1990)			
	CH	HERRMANN et al., Detection of <i>Neisseria gonorrhoeae</i> from Air-Dried Genital Samples by Single-Tube Nested PCR, <i>J. of Clinical Microbiology</i> , 34(10) :2548-2551 (Oct. 1996)			
	CI	IWEN et al., Evaluation of Nucleic Acid-Based Test (PACE 2C) for Simultaneous Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in Endocervical Specimens, <i>J. of Clinical Microbiology</i> , 33(10) :2587-2591 (Oct. 1995)			
	CJ	JEPHCOTT, A.E., Microbiological Diagnosis of Gonorrhoea, <i>Genitourin Med.</i> , 73 :245-252 (1997)			
	CK	KWOH et al., Transcription-based Amplification System and Detection of Amplified Human Immunodeficiency Virus Type 1 with a bead-Based Sandwich Hybridization Format, <i>Proc. Natl. Acad. Sci. USA</i> , 86(4) : 1173-7 (1989)			
	CL	LITTLE et al., <i>Clinical Chemistry</i> , 45(6) : 777-784 (1999)			
	CM	LIZARDI et al., <i>Bio Technology</i> , 6 : 1197-1202 (1988)			

Examiner Signature		Date Considered	
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Sheet	3	of	3	Attorney Docket Number	020187.0100/P-5677

CN	LIZARDI et al., <u>Mutation Detection and Single-Molecule Counting Using Isothermal Rolling-Circle Amplification</u> , <i>Nat. Genet.</i> 19(3) : 225-32 (1998)	
CO	SAIKI et al., <i>Science</i> , 230: 1350-1354 (1985)	
CP	SCHOONE et al., <u>Comparison of Dot Blot with in-situ Hybridization for the Detection of <i>Neisseria gonorrhoeae</i> in the Urethral Exudate</u> , <i>J. of Applied Bacteriology</i> , 66 :401-405 (1989)	
CQ	STARY et al., <u>Comparison of Ligase Chain Reaction and Culture of Detection of <i>Neisseria gonorrhoeae</i> in Genital and Extragenital Specimens</u> , <i>J. of Clinical Microbiology</i> , 35(1) :239-242 (Jan. 1997)	
CR	TOTTEN et al., <u>DNA Hybridization Technique for the Detection of <i>Neisseria gonorrhoeae</i> in Men with Urethritis</u> , <i>The Journal of Infectious Diseases</i> , 148(3) :462-471 (Sep. 1983)	
CS	WALKER et al., <u>Isothermal in-vitro Amplification of DNA by a Restriction Enzyme/DNA Polymerase System</u> , <i>PNAS</i> , 89 :392-396 (1992)	
CT	WALKER et al., <u>Strand Displacement Amplification-an Isothermal, in-vitro DNA Amplification Technique</u> , <i>Nucl. Acids Res.</i> , 20 :1691-1696 (1992)	
CU	WATSON et al., <u>Recombinant DNA</u> , <i>Scientific American Books</i> , New York, pages 67-69, 1992	
CV	WU et al., <i>Genomics</i> , 4 : 560-569 (1989)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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